PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0147-007.B.WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/CH 03/00048	International filing date *(day/month/year)* 23.01.2003	Priority date *(day/month/year)* 28.01.2002
International Patent Classification (IPC) or both national classification and IPC A61M1/28		
Applicant DEBIOTECH S.A. ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand 25.08.2003	Date of completion of this report 16.04.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Kroeders, M Telephone No. +31 70 340-1967

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CH 03/00048

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-24 received on 16.03.2004 with letter of 16.03.2004

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-24
	No:	Claims	-
Inventive step (IS)	Yes:	Claims	1-24
	No:	Claims	-
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	-

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Document WO-A-9906082, which is considered to represent the most relevant state of the art, discloses (cf. page 6, line 19 to page 16, line 7):

> automatic peritoneal dialysis sampling system (14, 30) adapted to automatically sample at specific time intervals volumetric fractions of dialysate contained in the peritoneum of a patient in order to improve the peritoneal dialysis for a given patient, wherein the peritoneal dialysis sampling system (14, 30) comprises a sampling container (30) and pumping means (P1) disclosed in combination with a series of valves (14, belonging to an automated peritoneal dialysis system) adapted to direct a certain quantity of fluid from a series of containers (S1, S2, G1, M1, M2) to a patient

The subject-matter of claim 1 differs from this disclosure in that the automatic peritoneal sampling system comprises multiple sampling containers and the series of valves are used to fill each of these containers.

In view of said difference, the subject-matter of claim 1 is new and meets the requirements of Article 33(2) PCT.

The differentiating features mentioned above have the purpose of automatically preparing and storing separate samples of dialysate liquid for later analysis.

None of the available prior art documents describes the physical storing of a plurality of dialysate liquid samples for later use, neither before nor after each sample has been analysed.

Therefore, the subject-matter of claim 1 involves an inventive step and the claim meets the requirements of Article 33(3) PCT.

The automatic peritoneal sampling system disclosed in claim 1 is industrial applicable and therefore the requirements of Article 33(4) PCT are met as well.

Claims 2 to 24 depend from claim 1 and refer to further embodiments of the automatic peritoneal sampling system described in claim 1 or a peritoneal dialysis system containing the automatic peritoneal sampling system of claim 1. Thus, claims 2 to 24 meet the requirements of Articles 33(2), (3) and (4) PCT for the same reasons explained above.